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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/053,088 | 01/18/2002 | Graham John Hamilton Melrose | 2354/141 (PF34527/02) | 6479 |

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EXAMINER

KUMAR, PREETI

ART UNIT PAPER NUMBER

1751

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/053,088

Applicant(s)

MELROSE ET AL.

Examiner

Preeti Kumar

Art Unit

1751

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/19/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Non-Final Rejection

1. Claims 1-13, 15-47 are pending.
2. Claims 44-47 are newly added.

Response to Amendment

3. The rejection of claims 1-43 under 35 U.S.C. 112, second paragraph, is withdrawn in light of applicant's amendment to the claims.
4. The rejection of claims 1-43 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,410,040 is withdrawn in light of applicant's arguments that the material limitations of the instant claims find written descriptive support in parent 10/009,139 filed February 16, 2000.
5. The rejection of claims 1-9 and 12-23 and 43 under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Melrose et al. (US 6,410,040) is withdrawn in light of applicant's arguments that the material limitations of the instant claims find written descriptive support in parent 10/009,139 filed February 16, 2000.
6. The rejection of claims 24-42 under 35 U.S.C. 103(a) as being unpatentable over Melrose et al. (US 6,410,040) is withdrawn in light of applicant's arguments that the material limitations of the instant claims find written descriptive support in parent 10/009,139 filed February 16, 2000.

7. The rejection of claims 1-13, 15-43,45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Manoury et al. (US 4,711,892) is maintained for the reasons recited in the previous office action and further explained below.

Response to Arguments

8. Applicant's arguments filed 2/19/2004 have been fully considered.

Applicants urge that Melrose et al. (US 6,410,040) is not available as prior art because applicant's arguments that the material limitations of the instant claims find written descriptive support in parent 10/009,139 (WO 01/60874) filed February 16, 2000. The rejection over Melrose et al. (US 6,410,040) is withdrawn. However the teachings of Melrose et al. is available in the equivalent WO 00/03723 which was published January 27, 2000. Please see the New Grounds of Rejection below.

Also applicants urge that the teachings of Melrose et al. (US 6,410,040 which is the equivalent of WO 00/03723) are drawn to a process that is different from that which is claimed by the instant claims. Please see applicant's arguments, page 11 last paragraph to page 12. However, examiner would like to point out that the instant claims are not drawn to a process, they are drawn to a composition. Furthermore, in response to applicant's argument that the reference fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., heating the starting polymer at a sufficient temperature and for a sufficient amount of time in a solvent...) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

And finally regarding the comment that it is improper to infer that the product of Melrose et al. (US 6,410,040 which is the equivalent of WO 00/03723) is the same as the claimed antimicrobial, examiner has shown that the prior art teaching of Melrose et al. illustrates poly(2-propenal, 2-propenoic acid) dissolved in polyethylene glycol which is substantially identical to the material limitations of the instant claims. The MPEP states that once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection is made, the burden shifts to the applicant to show an unobvious difference. See MPEP 2113.

Finally applicant's urge on page 13 of the remarks filed 2/19/2004 that the teachings of Manoury et al. do not teach or suggest antibacterials that are polymers. However, contrary to applicants arguments, Manuory et al. illustrate in example 2 in col.3, where 3-(6-methoxy-3-pyridyl)-2-propenoic acid, methanol, and 3-(5-nitro-2-furyl)-2-propenal is added in solution. Accordingly the rejection has been maintained.

New Grounds of Rejection

Claim Objections

9. Claims 1-13, 15-47 are objected to because of the following informalities:
Examiner notes that some of the claims recite antimicrobial composition, while others recite simply antimicrobial. It appears Applicants claims are drawn to an antimicrobial composition and thus, all the pending claims should recite antimicrobial composition. Just reciting the adjective antimicrobial does not make grammatical sense. Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 1-9 and 12-23 and 43-47 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Melrose et al. (WO 00/03723).

Melrose et al. teach a method for the preparation of compositions of poly(2-propenal, 2-propenoic acid) comprising the method steps of dissolving the poly(2-propenal, 2-propenoic acid) in aqueous base, adding an organic compound containing one or more hydrophobic groups, and subsequently acidifying the solution, whereby interaction between the hydrophobic groups of the organic compound and the poly(2-propenal, 2-propenoic acid) prevents precipitation of the poly(2-propenal, 2-propenoic acid) occurring at pH >5.5 and the solution is consequently stable over a broad pH range. See abstract. Specifically, Melrose et al. teach polymeric compounds having a polyacrolein sub-unit in aldehyde, hydrated, hemi-acetal or acetal form and having biostatic or biocidal properties and the biostatic and/or biocidal uses of these compositions. See page 2, ln.10-25.

Melrose et al. teach that antimicrobial compositions may be used as preservatives, or as the active ingredients in disinfectants, dermatological compositions including sun screen formulations or antiseptic formulations, or in animal feed additives.

Generally these antimicrobial compositions must: be stable; be efficacious in killing micro-organisms within a specified time; be safe, that is be reasonably free of toxicity which may be caused by the trans-dermal migration of low molecular weight ingredients into the blood-stream so as to manifest toxicity, antigenicity, allergy, irritation or inflammation; have minimal odour; and in some dermatological preparations, have the property of sun screening and minimise adverse dermatological effects from the generation of free-radicals. See pages 2-3.

Specifically regarding claims 12-13 and 15-22, Melrose et al. teach that the composition further comprises one or more of ethylene diamine tetra acetic acid, a lower alkanol, a phenol, isothiazolinones and glutaraldehyde, whereby the composition exhibits a synergistic increase in antimicrobial activity. See page 5 and example 7, page 17.

Regarding claims 5-9, 23 and 43, Melrose et al. illustrate in example 8 the effects of the presence of poly(2-propenal, 2-propenoic acid) on the migration of various agents across a model for skin wherein (a) poly(2-propenal, 2-propenoic acid) (0.5 g) was dissolved in polyethylene glycol 1000 (10 g) by stirring at 70.degree. C., then sodium hydroxide micro-pellets (50 mg) were added and stirred for 2 minutes, and then octyl methoxy cinnimate (10 g; sunscreen agent) was added, followed by a mixture of the polymeric emulsifiers PEMULIN TR1 and CARBOPOL 2984 (0.5 g; equal parts) whilst maintaining the temperature at 70.degree. C./15 minutes. See page 19. Accordingly, the broad teachings of Melrose et al. appear to anticipate the material limitations of the instant claims.

Alternatively, even if the broad teachings of Melrose et al. are not sufficient to anticipate the material limitations of the instant claims, it would have been nonetheless obvious to one of ordinary skill in the art, to arrive at an antimicrobial composition comprising the specified amounts of antimicrobial as recited by the instant claims because Melrose et al. teach poly(2-propenal, 2-propenoic acid) which are useful preservatives, or as the active ingredients in disinfectants, dermatological compositions including sun screen formulations or antiseptic formulations, or in animal feed additives meeting regulatory standards.

12. Claims 24-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Melrose et al. (WO 00/03723).

Melrose et al. are relied upon as set forth above. However, Melrose et al. do not specifically teach a method of treating gastrointestinal disease in an animal with compositions of poly(2-propenal, 2-propenoic acid) and the specified dosages for administration as recited by the instant claims.

However, Melrose et al. illustrate by example microbiological test of poly(2-propenal, 2-propenoic acid) with various organisms such as *P. vulgaris*, *E. coli*, *Ps. Aeruginosa*. See Table 10A, page 23.

Thus, one of ordinary skill in the art would have been motivated to use a composition comprising poly(2-propenal, 2-propenoic acid) in a method of treating gastrointestinal disease in animals because Melrose et al. suggest the use of poly(2-propenal, 2-propenoic acid) as an antimicrobial agent against various organisms such

as *P. vulgaris*, *E. coli*, *Ps. Aeruginosa* which are known to cause gastrointestinal disease in animals.

Double Patenting

13. Claims 1-13, 15-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of WO 00/03723. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-25 of WO 00/03723 encompass the material limitations of the instant claims. The material limitations of the instant claims and the patented claims of WO 00/03723 are both drawn to poly(2-propenal, 2-propenoic acid) dissolved in a solvent comprising one or more hydroxyl groups.

Conclusion

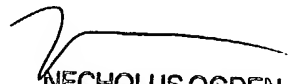
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Preeti Kumar whose telephone number is 571-272-1320. The examiner can normally be reached on M-F 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra N. Gupta can be reached on 571-272-1316. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Preeti Kumar
Examiner
Art Unit 1751

PK


NICHOLUS OGDEN
PRIMARY EXAMINER